REMARKS

This Amendment is submitted in reply to the final Office Action mailed on August 2, 2006. A Request for Continued Examination (RCE) and a petition for a three month extension is submitted herewith. The Director is authorized to charge $790.00 for the RCE fee and $1,020.00 for the petition for three month extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-780 on the account statement.

Claims 1, 3-4, 6-10 and 13-20 are pending in this application. Claims 2, 5 and 11-12 were previously canceled. In the Office Action, Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. §103. In response Claims 1, 10, 13 and 20 have been amended. This amendment does not add new matter. For the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Applicants have amended independent Claims 1, 10, 13 and 20 for clarification purposes. The amendment is supported in the specification, for example, at page 2, lines 15-33.

In the Office Action, Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over JP 002158762 ("*JP '762*") in view of U.S. Patent No. 6,787,158 to Erdmann et al. ("*Erdmann*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claims 1, 10, 13 and 20 recite, in part, a composition comprising hydrolysed sweet whey protein from which caseino-glyco-macropeptide (CGMP) has been removed. This provides a composition with reduced threonine (e.g. reduced nitrogen load) and increased tryptophan content and can be a hypoallergenic infant formula. In contrast, Applicants respectfully submit that, even if combinable, the cited references fail to disclose or suggest every element of the present claims. To further clarify the disclosure of *JP '762*, Applicants submit an English translation of the *JP '762* (attached as Exhibit A)

Applicants submit an Affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit B) that demonstrates the deficiencies of the prior art with respect to the present claims. As supported by the *Affidavit*, *JP '762* and *Erdmann* fail to disclose or suggest a hydrolysed sweet whey protein from which caseino-glyco-macropeptide (CGMP) has been removed as required, in part, by Claims 1, 10, 13 and 20.

JP '762 is directed to a preparation of a composition for babies and infants having disorders such as urea disorders and kidney disorders. This explains the presence in the composition of a wide range of the free amino acids, the suggested proportions of lipid and carbohydrate that may be used (which are different from those usually found in infant formula) and the suggestion that honey can be added to disguise the bitter taste of the amino acids.

As supported by the *Affidavit*, *JP '762* neither teaches nor suggests a hydrolyzed sweet whey protein as required, in part, by Claims 1, 10, 13 and 20. The Patent Office admits same. See, Office Action dated January 31, 2006, page 9, lines 7-8. *JP '762* also fails to teach or suggest hydrolysed sweet whey protein from which CGMP has been removed. Although *JP '762* mentions that the composition may be easily digested and utilized by the babies, *JP '762* does not disclose that the protein is hydrolysed in any preparation step. Finally, *JP '762* does not disclose a milk protein having 5% or more of amino acids as tryptophan as required, in part, by the present claims. Consequently, *JP '762* is deficient with respect to the presently claimed subject matter.

As supported by the *Affidavit*, *Erdmann* fails to disclose or suggest a hydrolyzed sweet whey protein from which caseino-glyco-macropeptide (CGMP) has been removed as required, in part, by Claims 1, 10, 13 and 20. *Erdmann* is directed to a process for treatment of a lactic raw material. The process relates to the extraction of glycomacropeptide (GMP) from the raw material by subjecting the material in a solution having a pH of about 1 to 4.5 to an anionic resin to which GMP selectively binds.

Nevertheless, *Erdmann* fails to disclose or suggest a hydrolysed sweet whey protein as a starting material for its process by which the CGMP is removed. As supported by the *Affidavit*, the only hydrolysed product disclosed in *Erdmann* is a raw material produced by hydrolysis by a protease of native casein. This raw material taught in *Erdmann* is the product of a process in which skimmed milk is acidified to precipitate the casein leaving the whey product in solution. In this process, unlike the enzymatic precipitation of casein from skimmed milk, CGMP is not cleaved from kappa casein and all the casein proteins are precipitated leaving only the whey proteins in solution. The expression "native casein" is used to describe these intact casein proteins precipitated by acidification. *Erdmann* proposes that native casein may be subject to

hydrolysis by a protease to liberate the CGMP from the intact casein proteins and that the result of such hydrolysis may be used as the starting material in the process disclosed in *Erdmann*.

Erdmann also fails to disclose or suggest that the final modified sweet whey, which is a by-product of removal of the CGMP, is subsequently hydrolysed. Applicants respectfully disagree with the Patent Office's assertion that *Erdmann* teaches that hydrolyzed sweet whey can be obtained after the extraction or separation of the CGMP. See, Office Action, page 6, lines 12-14. The Patent Office has provided no evidence in *Erdmann* regarding this statement, and *Erdmann* fails to teach or suggest anywhere hydrolyzing its final separated protein product or any benefit in doing so.

The Patent Office appears to place great emphasis on the appearance in *Erdmann* at column 2, lines 21-28 of the words "the product of hydrolysis by a protease" to support the assertion that *Erdmann* discloses or suggests the use of hydrolysed sweet whey protein. In fact, Applicants respectfully submit that, if the passage is read carefully, it will be seen that it is discussing suitable "lactic raw materials" that can be used as starting materials for the separation process disclosed in *Erdmann*. *Erdmann* at column 2, lines 10 to 21, deals with the use of various forms or derivatives of sweet whey protein as a starting material. Then, *Erdmann* teaches at lines 22 to 28 that an alternative starting material could be casein obtained by acid precipitation of skimmed milk.

In the cheese-making process, the casein curd may be precipitated from the whole milk either by acidification or by use of the enzyme rennet. If rennet is used, it has the additional effect of cleaving a large peptide, CGMP, from kappa casein and this peptide remains in solution with the whey proteins. These soluble proteins are collectively referred to as "sweet whey proteins" as the solution has a pH close to neutral. If acid is used, this cleavage does not occur, and the kappa casein precipitates intact with the other proteins. The soluble proteins, which do not include CGMP, are collectively referred to as "acid whey proteins" as the solution has a considerably lower pH than sweet whey. It may be seen that, in this latter case, the CGMP, which is the desired end-product of the *Erdmann* process, forms part of the precipitated casein proteins. *Erdmann* at column 2, lines 22 to 28, is suggesting that the precipitated casein can be used as a starting material if it is hydrolysed with a protease to release the CGMP.

Consequently, there is no disclosure in *Erdmann* of a process of making hydrolysed sweet whey protein in accordance with the present claims contrary to what is stated by the Patent Office.

For the reasons discussed above, even if combinable, *JP '762* and *Erdmann* do not teach, suggest, or even disclose all of the elements of the present claims, and thus, fail to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1, 3-4, 6-10 and 13-20 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____
Robert M. Barrett
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Dated: January 16, 2007

EXHIBIT 1

(19) Japan Patent Office
(12) Public Patent Bulletin (A)

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(43) 30th September 1983

(51) Int. Cl[3]	Identification number	JPO File number
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(54) Nutritive Composition for Infant

(21) Patent Application 1982-46275
(22) Filed 25th March 1982

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Specification

1. Title of the Invention

Nutritive Composition for Infant

2. What is claimed is:

The present invention is a nutritive composition for infant, characterized in that its weight is based on proteins, being total nitrogenous compounds, the nitrogenous compounds it contains being a source of protein in the following composition, and in which there is a lowered component ratio of protein.

Casein and casein salts (casein protein)
24-32 (% of weight)
Whey powder (whey protein)

	30-40
L-isoleucine	2.2-3.0
L-leucine	8.5-11.3
L-methionine	0.3-0.4
L-cystine	2.4-3.2
L-phenylalanine	2.7-3.7
L-tyrosine	2.7-3.7
L-threonine	3.0-4.0
L-tryptophan	0.5-0.7
L-valine	4.0-5.4
L-arginine	3.9-5.3
L-histidine	1.4-2.0

3. Detailed description of the invention

The present invention is a nutritive composition for infant that is highly superior in terms of digestive absorption.

In greater detail, the present invention is a nutritive composition for infants as a source of protein, comprising natural milk proteins and amino acids and containing fats, carbohydrates, minerals, vitamins and other nutrients.

One of the aims of the present invention is to provide a nutritive composition that contains an optimal source of protein in the form of a therapeutic feed for infant patients suffering from urea cycle anomalies that occur in the liver. A further aim of the present invention is to provide a nutritive composition for infants with nutritional disorders.

In general, when infants suffer from urea cycle anomalies, ammonia levels in the blood and cerebro-spinal fluid become raised, and a low protein diet is necessary in order to lower these ammonia levels, this means that the infant then requires a sufficient intake of essential amino acids. Furthermore, proteolysis and digestive capabilities in infants with nutritional disorders may be lowered due to an insufficient intake of essential amino acids.

The present invention is a nutritive composition for infant, characterized in that its weight basis is on proteins, being nitrogenous compounds, the nitrogenous compounds it contains being a source of protein in the following composition, and in which there is a lowered component ratio of protein, as a nutritive composition for treating the aforementioned types of nutritional disorders in infants.

Casein and casein salts (casein protein)	
	24-32 (% of weight)
Whey powder (whey protein)	
	30-40
L-isoleucine	2.2-3.0
L-leucine	8.5-11.3
L-methionine	0.3-0.4
L-cystine	2.4-3.2

L-phenylalanine	2.7-3.7
L-tyrosine	2.7-3.7
L-threonine	3.0-4.0
L-tryptophan	0.5-0.7
L-valine	4.0-5.4
L-arginine	3.9-5.3
L-histidine	1.4-2.0

The present invention does not just reduce the levels of protein ingested, in addition to providing natural proteins that are beneficial in terms of digestive absorption; it also succeeds in reducing total protein levels whilst providing supplementary essential amino acids. Preparations consisting of only amino acids have an unpleasant smell and a bitter taste, making them hard to administer, and in solution they have a high osmotic pressure which makes them unsuitable for administering to infants.

The present invention, a nutritive composition, combines natural proteins and amino acids making it very easy for infants to take; it can be made more palatable with the addition of a small amount of honey which makes it easier to administer.

Moreover, the present invention, a nutritive composition, can be administered orally, or by enteral intubation.

The casein used in the present invention is generally in the form of salts but in order to dissolve the casein, sodium salts, potassium salts and calcium salts can be used to obtain good dispersibility and solubility.

Whey powder is obtained from the whey portion of cow's milk once the casein has been removed from it. It may be used in a further demineralised state or with lactose removed.

In addition, the amino acids used are generally in a free form, but it is possible to use histidine in hydrochloride form.

The basic composition of the present invention, a nutritive composition for infant, comprises casein, whey powder, and the necessary formulation of amino acids, but in addition, carbohydrates, fats, minerals, vitamins and other ingredients may be added where appropriate. For carbohydrates, it can be used combined with lactose and a starch decomposition product, honey or other energy source, with their usage weight being 40-60% of weight.

For fats, sunflower oil, palm oil, corn oil, soybean oil, coconut oil and other vegetable oils, lard and other animal fats and equivalent MCT fats (medium-chain triglyceride) can be used. The usage amount for these is 20-50% of weight.

In addition, in order to emulsify the amino acids and the fat chains, sugar esters, monoacylglycerol, lecithin and other surfactants are added in order to provide optimal emulsification and homogenisation at the time when the composition is used.

For vitamins, in order to satisfy the "Recommended International Standards for Foods for Infants and Children" CAC/RS72-1976 of the Codex Alimentarius Commission of

the Joint FAO/WHO Food Standards Programme (hereafter referred to as "recommended standards"), vitamins A, B_1, B_6, B_{12}, C, D, E, K_1, pantothenic acid, niacin, folacin, biotin, inositol, choline (may also be substituted with lecithin) and others may be used. For all vitamin types a usage amount of 0.1% of the weight is sufficient.

For minerals, in order to satisfy the recommended standards, ferrous sulphates, sodium ferrous citrate and other iron salts, copper gluconate and other copper salts, zinc sulphate, zinc chloride and other zinc salts, manganese acetate and other manganese salts, cobalt acetate and other cobalt salts, potassium iodide, potassium carbonate and other potassium salts and iodides, magnesium chloride and other magnesium salts, trisodium citrate, sodium chloride and other sodium salts, calcium glycerophosphate, calcium carbonate, calcium chloride and other calcium salts and chlorides, potassium dihydrogen phosphate, dipotassium hydrogen phosphate and other phosphates and potassium salts can be used. For all minerals the usage amount is 2-3% of weight.

Each of the above ingredients are mixed together uniformly in a powder preparation to make up the nutritive composition for infant.

The present invention, a nutritive composition for infant, is a powder preparation, the standard dose of which is a concentration of 15%W/V dissolved in water and administered. The dose can either be administered orally, or by enteral intubation.

The present invention, a nutritive composition for infant, can lower ammonia concentrations in the blood and cerebro-spinal fluid of infants through administration to patients with urea cycle anomalies and can also be used as a feed.

In addition, the present invention, a nutritive composition for infant, can be administered to infants that are undernourished, in order to provide a well-balanced intake of essential amino acids even in severe cases, where proteins are restricted, for example due to renal insufficiency, with the use of only a small amount of protein. Following is a practical example of the present invention

Practical Example 1.

The following ingredients mixed together uniformly in a preparation.

Sodium caseinate	2.243g
Whey powder	3.031g
L-isoleucine	0.157g
L-leucine	0.582g
L-methionine	0.016g
L-cystine	0.165g
L-phenylalanine	0.189g
L-tyrosine	0.207g
L-threonine	0.230g
L-tryptophan	0.037g
L-valine	0.275g
L-arginine	0.276g

L-histidine hydrochloride	0.136g
MCT fat	16.660g
Plant oil	27.568g
Lactose	53.54g
Honey	3.270g
Niacinamide	6.0mg
Vitamin B_2	0.91mg
Vitamin B_{12}	7.9 μg
Inositol	12.49mg
Biotin	0.06mg
DL-a-Tocopherol	6.0mg
Vitamin A and Vitamin D compound	6.711mg
Vitamin K_1	114 μg
Thiamine hydrochloride (V. B_1)	0.72mg
Pyridoxine hydrochloride (V. B_6)	0.43mg
Ascorbic acid (V. C)	54.0mg
Folacin	0.24mg
Calcium pantothenate	2.40mg
Sodium ferrous citrate	80.0mg
Potassium iodide	0.11mg
Calcium glycerophospate	427.3mg
Calcium carbonate	565.58mg
Calcium hydroxide	41.4mg
Calcium chloride dihydrate	33.0mg
Potassium dihydrogen phosphate	108.3mg
Dipotassium hydrogen phosphate	231.3mg
Hexahydrate magnesium oxide	294.0mg
Sodium chloride	207.9mg
Trisodium citrate dihydrate	44.1mg
Lecithin powder	90.0mg
Sugar ester	225.0mg
Monoacylglycerol	114.0mg
Copper sulphate pentahydrate	1.552mg
Zinc chloride	51.3mg
Manganese acetate tetrahydrate	0.669mg
Cobalt acetate tetrahydrate	0.211mg

This nutritive composition for infant is dissolved 15% W/V in water at 40°C, and the dose administered to the infant either orally or enterally.

Agent: Chikao Toda, Patent Attorney

EXHIBIT 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Kuslys et al.
Appl. No.: 10/088,766
Conf. No.: 2286
Filed: June 20, 2002
Title: COMPOSITION COMPRISING CASEIN PROTEIN AND WHEY PROTEIN
Art Unit: 1645
Examiner: Jana A. Hines
Docket No.: 112843-043

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:
Ph.D, University of Berne, Switzerland (4/30/1988)
Post Doc, Paul Scherrer Institute, Würenlingen, Switzerland (1/31/1989)
Group leader Analytical Chemistry, Nestle PTC Konolfingen, Switzerland (2/1/1989)
Project Manager, Nestle PTC Konolfingen, Switzerland (7/1/1999)
Product Area Coordinator, Nestle PTC Konolfingen, Switzerland (6/1/2000)
Department Head Nutrition Unit, PTC Singen, Germany, (9/1/2004)

2. I am a named inventor of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated August 3, 2006 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the references cited therein as well as the pending claims. I believe that the obviousness rejection of Claims 1, 3-4, 6-10 and 13-20 under 35 U.S.C. §103(a) based on U.S. Patent No. JP 002158762 ("*JP '762*") in view of U.S. Patent No. 6,787,158 to Erdmann et

al. ("*Erdmann*") is based on a misunderstanding of the references and the pending claims. The basis for my opinion is set forth below.

4. The present invention is directed, in part, to a composition for an infant formula comprising whey protein, casein protein, free arginine, free histidine, and an ingredient selected from milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof. Methods of making and using the composition are also claimed.

5. In the present claims, the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed. This provides the advantage of a composition having a reduced threonine content and a proportionally enriched tryptophan content as compared to normal sweet whey and is therefore suitable as a protein source for infants. It has also surprisingly been found that by supplementing the sweet whey fraction with the free amino acids arginine and histidine, and either the free amino acid tryptophan, a milk protein that has a level of 5% or more of amino acids as tryptophan or a mixture thereof, the protein source has an amino acid profile which is close to that of human milk.

6. *JP '762* is directed to a preparation of a nutritive composition for babies and infants which is specifically suitable for the treatment of disorders such as urea cycle disorders and kidney disorders. As one having ordinary skill in the art, I believe that *JP '762* fails to disclose or suggest any hydrolyzed whey protein in accordance with the present claims. Moreover, *JP '762* neither teaches nor suggests using hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed. Although *JP '762* mentions that the composition may be easily digested and utilized by the babies, *JP '762* does not disclose that the protein is hydrolysed in any preparation step.

7. *Erdmann* is directed to a process for treatment of a lactic raw material to separate glycomacropeptide (GMP) therefrom by subjecting the raw material in a solution having a pH of about 1 to 4.5 to an anionic resin to which GMP selectively binds. As one having ordinary skill in the art, I believe that *Erdmann* fails to disclose or suggest a sweet whey protein from which

the CGMP has been removed hydrolysed and which is hydrolysed in accordance with the present claims. *Erdmann* fails to disclose or suggest either the use of a hydrolysed sweet whey protein as a starting material for the process disclosed therein or hydrolyzing the products of its process in a subsequent step.

8. The only hydrolyzed product disclosed in *Erdmann* is a raw material produced by hydrolysis by a protease of native casein. As one having ordinary skill in the art, I believe that this raw material taught in *Erdmann* is the product of a process in which skimmed milk is acidified to precipitate the casein leaving the whey protein in solution. In this process, unlike the enzymatic precipitation of casein from skimmed milk, CGMP is not cleaved from kappa casein and all the casein proteins are precipitated leaving only the whey proteins in solution. The expression "native casein" is used to describe these intact casein proteins precipitated by acidification. *Erdmann* proposes that native casein may be subjected to hydrolysis by a protease to liberate the CGMP from the intact casein proteins and that the result of such hydrolysis may be used as a starting material in the process disclosed in *Erdmann*. Moreover, *Erdmann* does not teach or suggest that the modified sweet whey which is a by-product of removal of the CGMP is subsequently hydrolysed, and there is no reason for *Erdmann* to hydrolyse any of its final obtained protein products.

9. For all the foregoing reasons, as one having ordinary skill in the art, it is my opinion that *JP '762* and *Erdmann* fail to teach or suggest the claimed composition comprising a hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed or methods of making or using the claimed composition.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 12/21/2006

Print Name Dr. Martinas Kuslys